2 IN 1 DANDRUFF- pyrithione zinc shampoo Vi-Jon

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Mountain Falls 311

Active ingredient

Pyrithione Zinc 1%

Purpose

Anti-dandruff

Use

helps prevent recurrence of flaking and itching associated with dandruff

Warnings

For external use only

When using this product

• do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

• condition worsens or does not improve after regular use as directed

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- shake well
- for maximum dandruff controll, use every time you shampoo
- wet hair, massage onto scalp, rinse, repeat if desired
- for best results use at least twice a week or as directed by a doctor

Inactive ingredients

water, sodium lauryl sulate, sodium laureth sulfate, glycol distearate, sodium chloride, zinc carbonate, sodium xylenesulfonate, amodimethicone, cocamidopropyl betaine, fragrance, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, citric acid, methylchloroisothiazolinone, methylisothiazolinone, blue 1, red 33

Disclaimer

This product is not manufactured or distributed by Procter & Gamble, distributor of Head & Shoulders

Adverse Reactions

Manufactured by: Vi-Jon, Inc.,

St. Louis, MO 63114

Questions or Comments? 1-888-593-0593

Made in the USA

with US and foreign parts.

311.007/311AL

principal display panel

mountain

falls

*Compare to Head

& Shoulders

helps

prevent

flakes

leaves hair

clean and

manageable

+

conditioner

pΗ

balanced

formula

2 in 1

dandruff

shampoo

with pyrithione zinc

smooth spice

23.7 FL OZ (700 mL)





pyrithione zinc shampoo

Product	Infor	mation
Product	1111101	IIIdUVII

HUMAN OTC DRUG NDC:11344-311 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

9	V			
1	Ingredient Name	1	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2)	RHZ5) (PYRITHIONE ZINC - UNII:R953	BO2RHZ5) P	YRITHIONE ZINC	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368 GB5141J)	
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC CARBO NATE (UNII: EQR32Y7H0 M)	
SODIUM XYLENESULFONATE (UNII: G4LZF950 UR)	
AMODIMETHICONE (800 CST) (UNII: 363Z2T48P7)	
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11 KX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GUAR HYDRO XYPRO PYLTRIMO NIUM CHLO RIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
MAGNESIUM CARBO NATE HYDRO XIDE (UNII: YQO029 V1L4)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-311- 15	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/23/2005	
2	NDC:11344-311- 21	88 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/23/2005	
3	NDC:11344-311-39	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2005	
4	NDC:11344-311- 35	700 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/23/2005	

OTC monograph final	part358H	06/23/2005	

Labeler - Vi-Jon (150931459)

Registrant - Vi-Jon (088520668)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon		088520668	manufacture(11344-311)	

Revised: 7/2020 Vi-Jon